UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

MYRTLE THOMPSON	:	
	:	**Civil Action No.1:13-cv-00602**
Plaintiff	:	
	:	**COMPLAINT AND JURY DEMAND**
	:	
v.	:	
	:	
DEPUY ORTHOPAEDICS , INC **700 Orthopaedic Drive** **Warsaw, Indiana 46581**	:	
	:	
And	:	
	:	
JOHNSON & JOHNSON **One Johnson & Johnson Plaza** **New Brunswick, NJ 08933**	:	
	:	
Defendants	:	

Plaintiff, by and through counsel, and for her complaint against Defendants Depuy Orthopaedics, Inc. and Johnson & Johnson (collectively "Defendants") alleges as follows:

PARTIES AND JURISDICTION

1. Plaintiff Myrtle Thompson is a resident and citizen of Cincinnati, Ohio, in Hamilton County, Ohio.

2. Plaintiff alleges an amount in controversy in excess of Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

3. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New

Jersey 08933. Defendant Johnson & Johnson is a resident and citizen of New Jersey. Defendant Johnson & Johnson is the parent company of DePuy International Ltd. and Defendant DePuy Orthopaedics, Inc.

4. Defendant DePuy Orthopaedics, Inc. ("DePuy") is an Indiana corporation with its principal place of business at 700 Orthopedic Drive, Warsaw, Indiana 46581. Defendant DePuy is a resident and citizen of Indiana. DePuy is a subsidiary of Johnson & Johnson.

5. At all times relevant, Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous prosthetic devices, including Polymethylmethacrylate (PMMA) bone cement with antibiotic, trade name DePuy CMW 1 Gentamicin bone cement, for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

6. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

7. Venue in this district is appropriate under 28 U.S.C. §1391 because a substantial part of the events giving rise to this claim occurred in the district. Specifically, Plaintiff Myrtle Thompson received medical care and treatment in this venue.

FACTUAL BACKGROUND

8. On January 22, 2009, Plaintiff Myrtle Thompson, at the age of 48, underwent left knee replacement surgery. As part of the knee replacement surgery, Plaintiff's surgeon used bone cement; specifically, DePuy CMW 1 Gentamicin bone cement. (See exhibit A).

9. The bone cement used in Plaintiff's original surgery was manufactured by DePuy International, Ltd., a subsidiary of Defendant Johnson & Johnson, and distributed in the United States by DePuy Orthopaedics, Inc., under the trade name DePuy CMW 1 Gentamicin bone cement.

10. In late 2011, Plaintiff Thompson complained to her physician that she was having aching and throbbing pain in her left knee. She underwent an x-ray of her left knee which showed the knee replacement device to be in good position.

11. In March 2012, Plaintiff Thompson followed up with her physician again regarding the persistent aching and throbbing pain in her left knee. Again, an x-ray of her left knee showed the knee replacement device to be in good position.

12. In April 2012, Plaintiff underwent a bone scan which showed a loosening of the tibial component of the knee replacement. As a result of the loosening, Plaintiff's physician recommended Plaintiff undergo knee revision surgery.

13. On May 24, 2012, Plaintiff underwent a total revision knee surgery. Plaintiff's physician noted that the previously implanted "tibial component had loosened from the bone" due to failure of the bone cement to properly adhere to the surface, causing the pain and disability that necessitated the knee revision surgery. The operative reports specifically notes that "[t]he tibial component . . . was grossly loose,

and as soon as the polyethylene liner was removed the tibial component could just be lifted up off the tibial cement."

14. Thus, as a direct and proximate result of Defendants' failed and defective bone cement, Plaintiff was required to undergo a total knee revision surgery just three years after her original knee replacement surgery.

15. As a direct and proximate result of Defendants' failed and defective bone cement, Plaintiff has suffered significant harm, conscious pain and suffering, physical injury and bodily impairment.

16. As a direct and proximate result of Defendants' failed and defective bone cement, Plaintiff Thompson had to undergo a premature revision surgery of her prosthetic knee, causing further permanent impairment and weakness in her ligaments, bone and muscles.

17. As a direct and proximate result of Defendants' failed and defective bone cement, Plaintiff Thompson had to undergo revision surgery only three years after her original replacement knee surgery. Due to the unexpected and premature failure of Defendants' bone cement, Plaintiff faces a potential of more knee replacement surgeries in the future.

18. As a direct and proximate result of Defendants' failed and defective bone cement, Plaintiff Myrtle Thompson has suffered significant mental anguish and emotional distress and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

19. As a direct and proximate result of Defendants' failed and defective bone cement, Plaintiff Myrtle Thompson has also incurred medical expenses and other

economic harm, and will continue to incur such expenses and other economic harm in the future.

20. Plaintiff Myrtle Thompson's injuries as described herein qualify as a permanent and substantial physical deformity, loss of use of a limb, and/or loss of use of a bodily organ system.

The DePuy Gentamicin Bone Cement

21. Defendants' Gentamicin bone cement is considered a Class II medical device under 21 CFR § 860 and 21 CFR § 888.3027.

22. Defendant DePuy received marketing approval from the FDA for its Gentamicin bone cement under Section 510(k) of the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. § 360 *et seq*.

23. The 510(k) approval process by the FDA is regarded as a simplified application process, which does not require extensive review and approval by the FDA. The 510(k) approval is basically a "grandfathering" process, in which the manufacturer is only required to demonstrate that the device to be marketed is substantially equivalent to a device marketed prior to May 28, 1976. If so, FDA allows the product to be marketed but does not actually approve the design.

24. On or about June 30, 2003, Defendant DePuy submitted a 510(k) premarket notification for its DePuy 1 Gentamicin bone cement. According to the 510(k) submission, "DePuy 1 Gentamicin Bone Cement is a self curing cement, to which one gram of Gentamicin is added in 40 grams PMMA (Polymethyl methacrylate) cement for allowing the seating and securing of a metal or plastic prosthesis to living bone."

25. On or about September 29, 2003, the FDA found the DePuy 1 Gentamicin bone cement to be substantially equivalent to legally marketed predicate devices and granted marketing approval.

26. On or about June 17, 2004, Defendant DePuy submitted a 510(k) premarket notification for its DePuy 1 Gentamicin Bone Cement. The reason for this new 510(k) submission was that "[t]he Gentamicin Sulphate used in the cements is to be changed from micronised particles to non-micronised particles. Based on similarities in design, material, manufacturing method and intended use, DePuy believes that the DePuy 1 Gentamicin . . . manufactured with non-micronised are substantially equivalent to the previously cleared antibiotic bone cements manufactured with micronised Gentamicin."

27. On or about July 1, 2004, the FDA found the DePuy 1 Gentamicin bone cement as amended with non-micronized antibiotic particles to be substantially equivalent to legally marketed predicate devices and granted marketing approval.

28. On or about October 24, 2005, Defendant DePuy submitted a 510(k) premarket notification for its DePuy CMW 1 Gentamicin bone cement. As described in the 510(k), "DePuy 1 Gentamicin Bone Cement is a self-curing cement. The cement allows the seating and securing of a metal or plastic prosthesis to living bone. The following modifications are being made: DePuy CMW 1 Gentamicin will be made available in a 20 gram presentation in addition to the previously cleared 40 gram presentation. Changes are being made to the formulation of the bone cement liquid component."

29. DePuy's October 24, 2005 510(k) submission for the DePuy CMW 1 Gentamicin bone cement lists "DePuy 1 Gentamicin bone cement (now branded DePuy CMW 1 Gentamicin Bone Cement)" as the substantially equivalent device.

30. On or about November 22, 2005, the FDA found the DePuy CMW 1 Gentamicin bone cement to be substantially equivalent to legally marketed predicate devices and granted marketing approval.

31. Pursuant to the § 510(k) approval process, Defendant was responsible for complying with the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act).

Federal Requirements

32. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

33. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

34. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in

order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. § 360i.

35. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing practice (CGMP), as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. *See* 21 U.S.C. § 360j(f).

36. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 *et seq*. As explained in the Federal Register, because the CGMP regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and

manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

37. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

38. The regulations under 21 CFR Part 820 include, but are not limited to, requiring Defendants to:

a. establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. 21 CFR § 820.5;

b. establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. 21 CFR § 820.30(a);

c. establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. 21 CFR § 820.30(d);

d. establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements. 21 CFR § 820.30(f);

e. establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review

and approval of design changes before their implementation. 21 CFR § 820.30(i); and

f. develop, conduct, control, and monitor production process to ensure that a device conforms to its specifications. 21 CFR § 820.70(a).

39. Upon information and belief, Defendants' Gentamicin bone cement is adulterated pursuant to 21 U.S.C. § 351 because, among other things, Defendants failed to comply with the numerous regulations under 21 CFR § 820 regarding product design and manufacturing.

40. Upon information and belief, Defendants' Gentamicin bone cement is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

41. As a result of Defendants' failure to establish and maintain CGMP, Defendants' Gentamicin bone cement was defective and failed, resulting in a failure to properly adhere to the bone and/or prosthetic device, causing loosening of the device, and injury to Plaintiff.

42. Upon information and belief, Defendants' Gentamicin bone cement, is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY: DEFECTIVE MANUFACTURING ORC § 2307.74 et seq.

43. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

44. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of prosthetic devices including the DePuy Gentamicin bone cement, for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

45. The DePuy Gentamicin bone cement, manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer and/or applicable federal requirements for these prosthetic devices, posing a serious risk of injury and death.

46. The DePuy Gentamicin bone cement was defective in manufacturing and deviated in a material way from the design specifications and/or performance standards such that the bone cement failed to adhere to the bone and/or prosthetic device, caused loosening of the device, and injury to Plaintiff.

47. Defendants' manufacturing change in the gentamicin sulphate used in the bone cement from micronised particles to non-micronised particles rendered the bone cement defective in manufacturing.

48. Defendants' knew or should have known that such manufacturing change from micronised particles to non-mincronised particles would have resulted in a failure of the bone cement to properly adhere to the bone and/or prosthetic device and Defendants failed to adequately test the results of such manufacturing changes.

49. Defendants' manufacturing change in the formulation of the bone cement liquid component rendered the bone cement defective in manufacturing.

50. Defendants knew or should have known that such manufacturing change in the liquid component would have resulted in a failure of the bone cement to properly adhere to the bone and/or prosthetic device and Defendants failed to adequately test the results of such manufacturing changes.

51. As a direct and proximate result of Plaintiff Myrtle Thompson's use of Defendant DePuy Gentamicin bone cement, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants and Defendants' failure to comply with the federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

52. Defendants' actions and omissions as alleged in this complaint constitute a flagrant disregard for human life and safety, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY: DESIGN DEFECT
ORC § 2307.75 et seq.

53. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

54. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of prosthetic devices including the DePuy Gentamicin bone cement, for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

55. The DePuy Gentamicin bone cement, manufactured and supplied by Defendants, was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, and/or it failed to comply with federal requirements for these medical devices.

56. The DePuy Gentamicin bone cement was defective in design such that the risks of failure of the cement to adhere to the bone and/or prosthetic device exceeded the benefits of the device.

57. The DePuy Gentamicin bone cement was defective in design such that the failure of the cement to adhere to the bone and/or prosthetic device was more

dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

58. Defendants' design change in the gentamicin sulphate used in the bone cement from micronised particles to non-micronised particles rendered the bone cement defective in design.

59. Defendants knew or should have known that such design change from micronised to non-micronised particles would have resulted in a failure of the bone cement to properly adhere to the bone and/or prosthetic and Defendants failed to adequately test the results of such design change.

60. Defendants' design change in the formulation of the bone cement liquid component rendered the bone cement defective in design.

61. Defendants knew or should have known that such design change in the liquid component would have resulted in a failure of the bone cement to properly adhere to the bone and/or prosthetic and Defendants failed to adequately test the results of such design change.

62. The DePuy Gentamicin bone cement was defective in that at the time the product left the control of Defendants, a practical and technically feasible alternative design was available that would have prevented the harm for which Plaintiff Thompson seeks to recover without substantially impairing the usefulness or intended purpose of the product.

63. As a direct and proximate result of Plaintiff Myrtle Thompson's use of the DePuy Gentamicin bone cement, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and Defendants' failure to

comply with the federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

64. Defendants' actions and omissions as alleged in this complaint demonstrate a flagrant disregard for human life and safety, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY
DEFECT DUE TO INADEQUATE WARNING
ORC § 2307.76 et seq.

65. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

66. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of prosthetic devices including the DePuy Gentamicin bone cement for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

67. The DePuy Gentamicin bone cement, manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective due to inadequate warning or instruction because at the time it left the control of Defendants, Defendants knew or should have known that their bone cement was unreasonably dangerous due to its failure to properly adhere to the bone and/or prosthetic device.

68. Despite the fact that Defendants knew or should have known that their bone cement was unreasonably dangerous due to its failure to properly adhere to the

bone and/or prosthetic device, Defendants failed to exercise reasonable care to adequately warn consumers that its bone cement had an increased risk of injury and increased risk of a required revision surgery.

69. As a direct and proximate result of Plaintiff Myrtle Thompson's use of the DePuy Gentamicin bone cement, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

70. Defendants' actions and omissions in this complaint demonstrate a flagrant disregard for human life and safety, malice, and aggravate and egregious fraud, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY: DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS ORC § 2307.77 et seq.

71. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

72. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of prosthetic devices including the DePuy Gentamicin bone cement, for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

73. The DePuy Gentamicin bone cement, manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not

conform to representations made by Defendants concerning the product and/or with applicable federal requirements.

74. Plaintiff and/or Plaintiff Thompson's physicians, at the time they selected the DePuy Gentamicin bone cement to be used in Plaintiff's surgery, justifiably relied upon Defendants' representations that the DePuy Gentamicin was safe for use in knee replacement surgery and would conform to the representations regarding the character and quality of an appropriate bone cement to be used in knee replacement surgery.

75. As a direct and proximate result of Plaintiff Thompson's use of the DePuy Gentamicin bone cement and Plaintiff's and Plaintiff's physicians' reliance on Defendants' representations regarding the character and quality of the Gentamicin bone cement, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

76. Defendants' actions and omissions as alleged in this complaint demonstrate a flagrant disregard for human life and safety, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

FRAUDULENT / NEGLIGENT MISREPRESENTATION

77. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

78. Defendants, as the manufacturers of prosthetic bone cement being used by physicians and patients in orthopedic surgery, have a general duty not to deceive or misrepresent the safety, quality, characteristics, etc., of the bone cement they design, manufacture, distribute, sell, and supply.

79. In the exercise of reasonable care, Defendants should have known that its Gentamicin bone cement failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification or deviated from performance standards, yet Defendants, in breach of their general duty not to deceive, negligently misrepresented to Plaintiff and/or Plaintiff's physicians that its bone cement was safe and met all applicable design and manufacturing requirements.

80. Defendants negligently and/or fraudulent concealed from Plaintiff and Plaintiff's physicians that its Gentamicin bone cement lacked the proper safety, quality, and characteristics to properly adhere to bone and/or prosthetic devices.

81. Defendants' representations about the safety, quality, and characteristics of its Gentamicin bone cement were made with utter disregard and recklessness as to the truth of such representations.

82. Plaintiff and Plaintiff's physicians reasonably relied to their detriment upon Defendants' misrepresentations that the Gentamicin bone cement was safe for use and would perform to its intended purposes and standards.

83. As a direct and proximate result of Defendants' breach of its duty and negligent misrepresentations about its Gentamicin bone cement, Plaintiff Myrtle Thompson used Defendants' Gentamicin bone cement.

84. As a direct and proximate result of the failure of Defendants' bone cement, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

85. Defendants' actions and omissions as alleged in this complaint demonstrate a flagrant disregard for human life and safety, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff prays for relief as follows:

1) Compensatory and punitive damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $350,000.00 and punitive damages in excess of twice the compensatory damages award;
2) Economic damages in the form of medical expenses, out of pocket expenses, and other economic damages in an amount to be determined at trial of this action;
3) Attorneys' fees, expenses, and costs of the action; and
4) Such further relief as the Court deems necessary, just, and proper.

Respectfully submitted,

/s/Janet G. Abaray
Janet G. Abaray (0002943)
Melanie S. Bailey (0075821)
BURG SIMPSON ELDREDGE HERSH & JARDINE, PC
312 Walnut Street, Suite 2090
Cincinnati, OH 45202
(513) 852-5600
(513) 852-5611 (fax)

Attorneys for Plaintiff

JURY DEMAND

Plaintiff hereby demands a trial by jury.

/s/ Janet G. Abaray
Janet G. Abaray